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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,271	04/12/2001	William Widner	5455.210-US	4969

25907 7590 03/09/2006

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EXAMINER	
MONSHIPOURI, MARYAM	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/834,271	WIDNER ET AL.	
	Examiner	Art Unit	
	Maryam Monshipouri	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *74 and 78-93* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *74 and 78-93* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1-73, 75-77 have been canceled. Claims 74, 78-93 are still at issue and are present for examination.

Applicants' arguments filed on 8/22/2005 and 12/20/2005 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 74, 80, 82-84, 86-93 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hung (cited previously) in view Lereclus (cited previously) according to previous office actions. In traversal of this rejection applicant argues the following : that lacZ promoter in indeed present in both plasmids pH304 and PHT790'lacZ. However Figure 5 demonstrates that low levels of lacZ expression in a strain harboring pH304'lacZ and no improvement can be observed for a strain harboring pHT901'lacZ which has the cryIIIA "downstream region" situated downstream of the lacZ promoter. According to applicant one of ordinary skill in the art would expect to see a significant improvement if, in fact, a heterologous promoter is able to function in association with the cryIIIa "downstream region" and Figure 5 does not support this assumption. Therefore, in applicant's point of view Lereclus provides no evidence that cryIIIA

downstream region can be used with other promoters that are foreign to the cryIIIA "downstream region" to increase expression of a gene. In fact, Lereclus data (for example Figure 6) appears to be only specific for the cryIIIA promoter.

Finally, applicant concludes that since the references cited by the Examiner do not contain the requisite teaching they cannot be combined to render this invention obvious. Moreover there is no motivation to inserting "downstream region" of Lereclus into the DNA construct of Hung because there is no reasonable expectation of success of increasing expressing of a gene based on results obtained by Lereclus and therefore the rejection should be withdrawn.

These arguments were fully considered but once again were found **unpersuasive**. The point is well taken that in pH304'lacZ and pT7901'lacZ plasmids lacZ promoter were present. However, applicant is reminded of the scale in which the data in figure 5 is presented. As applicant himself/herself can observe the high level of beta galactose (beta gal) production in strain harboring pH7902'LacZ , which was higher than the two strains harboring the other two plasmids in Figure 5, somehow undermine the levels of galactose production in strain harboring pHT7901'. However, if applicant reviews column 17 of U.S. patent 6,140,104 (lines 25-30) , it is indicated that strain harboring pHT7901'LacZ produced a small but **significant** increase in beta gal production (i.e. 1200 Miller units from t-2 to t7.5 relative to 800 miller units beta gal activity produced in a strain harboring PH304'lacZ in the same period of time). Therefore, in contrast to applicants view, one of ordinary skill in the art did observe what he/she was expected (i.e. a significant increase in beta galactose production) when

he/she combined the effect of "downstream region" with that of the heterologous promoter of lacZ gene.

Once again applicant is reminded that *prima facie* case of obviousness does require overwhelming data in support of combining references but a mere motivation. Applicant can appreciate that 1200 miller units of activity (corresponding to stain harboring pH7901'lacZ) shows a 50% increase (1200-800/800=50%) in beta gal production relative to strain harboring pH304'lacZ and such increase is sufficient and significant enough to motivate one of ordinary skill to insert the "downstream region" of Lereclus into the Bacillus host comprising the DNA construct of Hung with a reasonable expectation of obtaining higher gene expression.

Finally, in view of previously stated teachings of Lereclus, as shown for example, in column 2 (lines 40-45) and column 5 (first paragraph) of U.S. Patent No. 6,140,104 that promoters from its construct may be both endogenous and exogenous (e.g. LacZ promoter) to the host used and in view of the data provided in Figure 5 and specially column 17 of said patent the examiner finds no reason to withdraw the rejection.

Claim 78 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Hung (cited previously) in view of Lereclus (cited above) further in view of Diderichsen (cited previously) according to previous office action. Therefore the rejection remains for the reasons provided above in addition to those provided previously.

Claim 85 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Hung (cited previously) in view of Lereclus (cited above) further in view of Jorgensen* according to previous office action. In traversal of this rejection applicant provides the

same arguments already addressed above. Therefore the rejection remains for the reasons provided above in addition to those provided previously.

Claims 89-90 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hung (cited previously) in view of Lereclus (cited above) further in view of Jorgensen according to previous office action. In traversal of this rejection applicant provides the same arguments already addressed above. Therefore the rejection remains for the reasons provided above in addition to those provided previously.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 74, 78-93 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 29-31 of U.S. Patent No.

5,955,310. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of issued claims embrace the scope of instant claims.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on 7:00 a.m to 4:30 p.m. except for alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weber Jon P. can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. Monshi

Maryam Monshipouri Ph.D.

Primary Examiner